EXHIBIT U

ATTACHMENT	G.	DICK	NA A	NIA	CEN	A E NIT
ALIACMMENT	n:	KISK	IVIA	IN M	CEL	иски

Attached is the original Risk Analysis which was prepared in 2000.		
The Risk Analysis will be updated according to ISO 14971: 2007.	Once it is available,	this
section will be updated.		

PMH-2008-08 ETHICON CONFIDENTIAL 166 of 251

ETHICO Name

a Johnson a Johnson company

P.O. BOX 151 SOMERVILLE, NEW JERSEY 08876-0151

November 11, 2000

Soft Prolene Mesh Device Final Design Safety Analysis (DDSA) - Summary

Overview:

The Soft PROLENE Mesh product is a single use (functioning as a bridging material) polypropylene mesh product that will be provided sterile, packaged ready for use.

An intermediate DDSA was completed and approved by the development team in March of 2000.

Intermediate DDSA Approvers:

- J. O'Malley Product Marketing
- C. Whiteman Process/Manufacturing Engineering
- M. Pamphille Corp. Quality Engineering
- K. Lessig Regulatory Affairs
- G. O'Brien Cornelia Quality Engineering
- R. Rousseau R&D

Also, a review of complaints for similar products (Mersilene and Prolene Mesh) was conducted in September of 2000 for Human Factors. (See attached report)

Conclusions:

There are 5 hazards, all at an acceptable level. No risk reduction was required.

Assumptions:

Assumptions are contained in the DDSA form (Pg. 14).

Mattmcfll

Quality Engineer

ETHICO N. INC.

a Johnson Johnson company

P.O. BOX 151 SOMERVILLE, NEW JERSEY 08876-0151

September 5, 2000

TO:

Matthew McGill

FROM:

R. Rousseau

CC:

Subject:

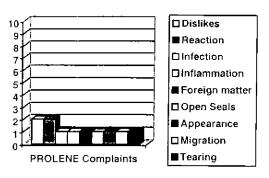
Soft PROLENE Mesh - Complaint Review of Similar Products for Human

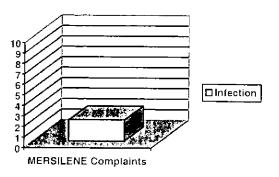
Factors

Matt.

As we had discussed during the project team meeting, held on 08/23/00, I have received an updated list of the product complaints for the standard PROLENE Mesh and for Mersilene Mesh from the World Wide Quality department(attached). The complaint listing was for the time period of May 1999 through August 2000. During this time there were a total of eleven (11) complaints for the PROLENE Mesh and two (2) complaints for the Mersilene Mesh product.

The type of complaints that were received are plotted in the following histograms:





The sales for this time period were also provided by Kiko Morillo (attached). During this time frame, $179,\!126$ sheets of PROLENE mesh and 7940 sheets of Mersilene mesh were sold. Based upon these sales results, the complaint rate for PROLENE mesh was 0.006% and for Mersilene mesh was 0.025%.

The lack of a single complaint type / trend indicates that Human factors induced failure modes are not typical in either the heavy weight(PROLENE) or light weight(Mersilene) meshes. If you have any questions, please contact me at 3215.

RobertRausseau

Staff Engineer, Suture Technologies

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OP650-070 CP1998SEF001 Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 2
	REVISION DATE: 11/8/00
Product Name:	Soft PROLENE Mesh
Product Code:	SPMXS (1x4), SPMS (2.5x4.5),
	SPMII (3x6), SPMH (6x6),
	SPMLI (10x10), SPMXXL (12x14)
RMC:	N/A
Project Leader;	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Process Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Matt McGill
Regulatory Affairs:	Karen Lessig
Product Marketing:	Kiko Morillo
DISPOSITION/APPROVAL:	
ant for sty	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Development Engineer/Scientist	design to be safe for use: (Check one:) Yes;: No.
Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use: (Check one:): Yes;: No.
<u> </u>	I deem this analysis to be true and a complete reflection of
mathycofill	facts as known at the time of this analysis. I find this device design to be safe for use; (Check one:) \checkmark : Yes;: No.
Quality Assurance Engineer	
Lanen E Linia	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Regulatory Affairs	design to be safe for use. (Check one:) : Yes;: No.

Soft Prolene Mesh DDSA, Rev. 2

Page 1

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PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 2
	REVISION DATE: 11/8/00
Product Name:	Soft PROLENE Mesh
Product Code:	SPMXS (1x4), SPMS (2.5x4.5),
	SPMII (3x6), SPMH (6x6),
	SPMLI (10x10), SPMXXL (12x14)
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Process Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Matt McGill
Regulatory Affairs:	Karen Lessig
Product Marketing:	Kiko Morillo
DISPOSITION/APPROVAL:	
Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
Chailatto Whilman Manufacturing Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
Quality Assurance Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use! (Check one:): Yes;: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use! (Check one:): Yes;: No.
Regulatory Affairs	10.

CP1998SEF001 010-6710 Appendix II

DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT

(Revision 2)

lescription of the overall device system) A non-absorbable polypropylene mesh, manufactured out of	ENE* monofilament fiber. The product is used to span and reinforce traumatic or surgical
DEVICE: (Provide a description of	3.5-mil diameter PROLENE* mo

wounds to provide extended support during and following wound healing (see attached Product Insert) SCOPE of the DESIGN SAFETY ASSESSMENT: (Define the scope of this risk assessment)

Subsystem This risk assessment was completed on (check one): X_ Device

Component

This DDSA is applicable to the Soft PROLENE mesh product and will identify any hazards associated with this new

product offering.

Define the intended use of the reviewed item:

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (see attached Product Insert)

Briefly describe the revision to the device or sub-system which preceded a revision to the DDSA:

monofilament fiber with a new knit pattern. This new pattern, coupled with the finer diameter fiber, yields a mesh The standard non-absorbable polypropylene mesh currently marketed is manufactured out of 5-mil PROLENE monofilament fiber. The construction utilized for the Soft PROLENE mesh is manufactured out of 3.5-mil product with larger porosity, lower fabric density and improved flexibility. Revision 2 is the final DDSA.

Soft Prolene Mesh DDSA, Rev. 2

Page 2

ACTIVITY	YES/NO	FILE	COMMENT
	N.	REFERENCE	
All qualitative and quantitative characteristics that could affect safety have	YES	D&D Plan &	Statement of Requirements
even networking their defined milits.		Material	& Product Characteristics
		Specification #729-007	
The intended use of the device is clearly defined, including:	YES	Product Insert	Indivotions Comment for Co. 1
Indications/Contraindications and intended use	1		DDOLTENIE MELL
The intended user, his required skill and training			CAOLEINE IMESA AND MICESHERE
Interaction of device with the patient as user:	_		iviesn
The operational, transport, cleaning and storage			
environments have been considered;			
Long term use of equivalent product has been considered from both the	YES	Sec Performance	Raw Materials and Indications
		Requirements/Clin	for device are the same as
Chilical/Scientific reports, both internal and published:		ical applications	Standard PROLENE mesh.
		of D&D	
The contact conditions and timing with the patient have been considered.	YES	See Performance	Raw Materials and Indications
		Requirements/Clin	for device are the same as
		ical applications	Standard PROLENE mesh.
Motoriale and assured to the		of D&D	
Practicals and components used for fabrication and manufacture have been considered.	YES	Soft PROLENE	Raw materials are chemically
(hemical noting anadiation committee of the		Mesh	unchanged – The Standard
Chemical nature, qualificative forfillulation, additives, processing aids,		Biocompatibility	PROLENE Resins utilized in
monomers, catalysts, residues:	•	Strategy	clear and blue pigmented sutures
Concentration, availability, toxicity:			have been utilized in the
Biodegradation aging and corrosion:			fabrication of this mesh.
Trevious use of this material, and long term effectiveness in equivalent			
application can be demonstrated:			
Appropriate Biocompatibility testing to EN 30993:			
The sterility of the device and its potential reuse, number of	YES	Product Insert	Raw materials are unchanged -
resterilizations possible and sterilization method, device storage, shelf-life,		Warnings section	Standard PROLENE Resin
and disposal have been considered.		ચ	
	_	1) Sterilization 2)	
		Storage Stability	

Soft Prolene Mesh DDSA, Rev. 2

clear and blue pigmented sutures tissue responses or new negative ong term implant effects are not Based upon the mechanical and Mersilene Mesh and exhibits a Mersilene Mesh and lower than develop this material, negative and suture pullout strengths of Raw materials are chemically construction exceeds the burst Raw materials are chemically PROLENE Resins utilized in flexibility that is greater than standard PROLENE mesh. chemical criteria utilized to unchanged - The Standard FG729-002 will be revised have been utilized in the unchanged. The revised fabrication of this mesh. MS 729-007 drafted See package Insert anticipated A/NN/A D&D - Statement of Requirements Product Insert Strategy N/AX/ANAN/A V/Z < Z X/A YES YES Y.Z YES YES YES YES Delayed or long term use, ergonomic and accumulative effects have been Interactions with other devices or drugs, and any potential problems have (cleaning, sterilization, use, maintenance, and disposal) are available. The need for routine maintenance or calibration, and the method of Surgical technique, labels, warnings and other instructions for use The accuracy and precision of measurement parameters and their A requirement or finished goods specification is available Manufacturing and Material specifications are available. interpretation has been considered provision has been considered A PBOM has been defined. been considered. considered Appendix []

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considered

Device marketing brochures, or other sales literature, have been

Sales Literature to be developed

Indications&Claim

Yes

s Defined

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OP650-t.

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

Soft Prolene Mesh DDSA, Rev. 2

Page 5

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Ot , 5-010 CP2000SEF002 Appendix III

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

trength of load-bearing materials The for the intended use? The type of energy transferred. The	<u> </u>		RESPONSE	ONSE		7 <u>8 </u>
12) Is the strength of load-bearing materials sufficient for the intended use? 13) Is energy delivered to and/or extracted from the patient? 14) Describe the type of energy transferred. 15) Is the energy output is controlled, in terms of quality, quantity, and time-terms of patient? 17) Is the device absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations? 19) Is the transfer rate (delivery/extraction) x of substances controlled?	- 1	ISSUE	N/A	YES	COMMENT	
13) Is energy delivered to and/or extracted from the patient? 14) Describe the type of energy transferred. 15) Is the energy output is controlled, in terms of quality, quantity, and timefunction 16) Are substances delivered to and/or extracted from the patient? 17) Is the device absorbable? 18) If the device is absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations? 19) Is the transfer rate (delivery/extraction) x of substances controlled?		12)Is the strength of load-bearing materials sufficient for the intended use?		×	The Soft PROLENE Mesh is indicated for the same applications as Mersilene Mesh. The material exceeds the strength specification for Mersilene Mesh - MS726-001 and has greater suture pull-out strength than Mersilene.	T
15) Is the energy output is controlled, in terms of quality, quantity, and timefunction 16) Are substances delivered to and/or extracted from the patient? 17) Is the device absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations? 19) Is the transfer rate (delivery/extraction) x of substances controlled? 20) What is the maximum/minimum substance		co and/c	×		If no, proceed to the next section.	
16) Are substances delivered to and/or extracted from the patient? 17) Is the device absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations? 19) Is the transfer rate (delivery/extraction) x of substances controlled? 20) What is the maximum/minimum substance		is controlled, ntity, and time				
device absorbable; have all of x levice is absorbable, have all of x rials identified above been tested ompatability at the appropriate ations? ransfer rate (delivery/extraction) x ances ed?		<pre>s substances delivered to racted from the ient?</pre>		×	Soft PROLENE Mesh	$\overline{}$
device is absorbable, have all of x rials identified above been tested ompatability at the appropriate ations? Transfer rate (delivery/extraction) x ances ed?		the device absorbable	×		If yes, please attach a listing of all by-products produced during the devices in-situ degradation	
<pre>iransfer rate (delivery/extraction) x ances ed? the maximum/minimum substance</pre>		18) If the device is absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations?	×		If yes, please identify the location of appropriate reports.	
the maximum/minimum substance		ransfer rate ances ed?	×		If yes, please describe how the transfer rate is controlled.	- ·
rate?					If appropriate, please attach required information.	,

Soft Prolenc Mesh DDSA, Rev. 2

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

RESPONSE	YES	If not, progetion.		If yes, please specify location of reports	If yes, please specify location of reports	X If not, please proceed to the	. 177 1	X No change to existing	polymer. Heat setting	process, utilized to stabilize the mesh is	executed at a temperature	<pre>dpp.oxlmately three times as great as the temperatures</pre>	x No change to existing materials	X No change to existing materials.	X Packaging unchanged from standard PROLENE Mesh.	X No change to existing materials - DHF: Storage Stability Committee mecting
RESP	N/A	×														
	ISSUE	21) Are biological materials processed by the device for subsequent re-use?	22) Is the device disposable?	23) Are those components contacting biological materials cleanable and sterilizable?	24) Are those components contacting biological materials compatible?	25) Is the device supplied sterile?	26) Identify the method of sterilization	27) Is the sterilization method compatible with	che materials?				28) Are the materials stable after sterilization?	29)Is the device design sterilizable?	30)Is the package designed to provide for sterilization of the device?	31) Has the shelf life of the system been determined?
	CHARACTERISTIC	6 Biological Materials				7 Sterility - Supplied Sterile										

Soft Prolene Mesh DDSA, Rev. 2

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Ol. .. .-010 CP2000SEF002 Appendix III

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

to the to the to the If not, please proceed If not, please proceed please proceed If yes, please specify If yes, please specify Lf yes, please specify please specify If yes, please specif f yes, please speci location of reports. ocation of reports location of reports COMMENT next section. next section next section If yes, If not, YES RESPONSE N/A × × × × × 35) Is the device to be sterilized by the user? methods utilized by the user of the device? ė Li 36) Is the method of sterilization and cycle cycle? 38)Does sterilization validation data exist temperature on the 45)What is the effect of pressure on system 34) Are there restrictions to sterilization to the number of the product during the system been 41) Is the device intended to modify the concentration on system performance? sterilization for the recommended sterilization on 44) What is the effect of atmospheric humidity the re-usable? sterilization specified? ISSUE 33) Are there limitations σĘ Jo methods of 43) What is the effect of patient environment? 37) Is the packaging of parameters defined? life system performance? 42) What is the effect system performance? the device 40) Has the shelf performance? use cycles? determined? 39) Were other examined? 32) Is CHARACTERISTIC Supplied Non-9 Environment Sterility Sterile

Soft Prolene Mesh DDSA, Rev. 2

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

<u> </u>		7			
			RESP	RESPONSE	
	CHARACTERISTIC	- 1	N/A	YES	COMMENT
∺ —— <u> </u> –	10 Measurements	es the	×		If not, please proceed to the next section.
		47) Is there interference of the desired parameter with other possible measurements?			If yes, please specify location of reports.
		the .nt o			What is the accuracy?
		49) Is the precision of the measurement known?			What is the precision?
	11 Interpretive	50)Are conclusions presented by the device based upon measurements, input, or acquired data?	×		rg .
ii	12 Interactions	51) Is the device intended to control or interact with other devices or drugs?	×		valuation reports. If not, please proceed to the next section,
<u> </u>		52)If the device is used with other devices or drugs, is there a potential interaction?	×		71.
		53)Does the interaction render any safety or functional changes to the device?			If yes, please specify
		54)Does the interaction render any safety or functional changes to the other device?			If yes, please specify
	13 Extraneous Unwanted Energy or Substances	55) Are there any unwanted outputs of energy or substances?	×		If not, please proceed to the next section.
					If yes, please define the limits.
 .		vibra			If ycs, please define the limits.
					If yes, please define the limits.
81 of 2		59)Does ionizing radiation affect the device output?			If yes, please define the limits.
		60)Does non-ionizing radiation affect the device output?			If yes, please define the limits.

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Soft Prolene Mesh DDSA, Rev. 2

OFv., p-010 CP2000SEF002 Appendix III

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET 10	
nð	

	RESPONSE	N/A YES COMMENT	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the effect.	If yes, please define the effect.	If yes, please define the effect.	X If not, please proceed to the next section.	If yes, please state the limits.	If yes, please state the limits.	If yes, please state the limits.	If yes, please state the limits.	If yes, please state the limits.	If yes, please state the limits.	X If yes, please specify	
O	~	ISSUE	0) 5	62)Do leakage currents affect the device output?	63)Do electric/magnetic fields affect the device output?	64)Do contact temperatures affect the device output?	65)Does discharge of chemicals affect the device output?	66)Does discharge of waste products affect the device output?	67)Does discharge of body fluids affect the device's output?	68) Is the device susceptible to environmental influences?	69)Do shipping temperatures affect device safety or functionality?	70)Does storage temperatures, humidity, or light affect device safety or functionality?	71) Does spillage on the device affect safety or functionality?	72)Do fluctuations in the power affect the device output or safety?	73) Does variation in the operating temperature, humidity, or light affect the device output or safety?	74)Does variation in the operating humidity affect the device output of safety?	75) Are there essential consumables or accessories associated with the device?	
		CHARACTERISTIC			<u> </u>		<u> </u>	9- 1		14 Environmental (Influences							15 Accessories 7	

010-6	Y)0SEF002	dix III
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QUALITATIVE & QUANTIFATIVE CHARACTERISTICS WORKSHEET

		RESP	RESPONSE	
CHARACTERISTIC	;	N/A	YES	COMMENT
lo Freventative Maintenance	76)Is preventative maintenance necessary?	×		If not, please proceed to the next section.
	77)Can the operator perform preventative maintenance?			
	78)Is a specialist needed to perform preventative maintenance?			
17 Calibration	79)Is calibration necessary?	×		If not, please proceed to the
	80)Can the operator calibrate the device?			
	81) Is an external calibration of the device needed?			
(82) Is the calibration frequency defined?			
18 Soitware	83) Does the device contain software?	×		If not, please proceed to the
	84) Can the operator access the software code?			
	85) Are there means to prevent the operator from modifying the code?			
19 Shelf-life	86)Does the device have a restricted shelf life?		×	5 years - No change to existing materials - DAF: Storage Stability Committee
	87)Does the package contain an indicator for stability?		×	- -
20 Long-term Effects	88) Are there any delayed or long-term user effects?	×		If yes, please specify.
	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED			
			1	

Soft Prolene Mesh DDSA, Rev. 2

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USE RELATED HAZARDS

Place an "X" in the box appropriate for the device being evaluated.	RESE	PONSE	ACTION
ISSUE	NO	YES	
Have safety or efficacy issues occurred in the use of predicate, or other similar, devices?	Х	-	If yes, explain how this design mitigates issues.
2) Could the user incorrectly setup the device that may potentially result in a safety or efficacy event?	х		If yes, explain actions needed to address this event
3) Identify the critical steps in setting up and operating the device. Can these functions be performed adequately by all of the intended users?		х	See steps at the end of this checklist.
4) Does this device replace an existing device for the same medical procedure or indication for use?]		If yes, continue to #5; if no, continue to #7
5) Does the device visually resemble the existing device?		х	If yes, continue to #6; if no, continue to #7
6) Will the device operate as intended if it is operated in the manne utilized for the existing device?	er.		If yes, continue to #7; if no, explain ramifications.
7) Is the user likely to use the device in a manner other than that described in the Instructions for Use?	х		If yes, explain ramifications
8) Is special training needed for the safe and effective use of the device?	х		If yes, provide plan for accomplishing this training
9) If storage and maintenance requirements are not followed, could use of the device result in an unsafe or ineffective use?	х		If yes, provide plan to mitigate the event.
10) Is safe and effective use of the device complex? Under high stress conditions, could the user become confused such that the device results in an unsafe condition?	x		If yes, provide plan to mitigate the event
11) Are the auditory and visual alarms appropriate for all users and use environments?	Х	Į.	Device is an implant and does not have alarms.
12) If necessary device accessories are expired, damaged, missing, or different from those recommended, could use of the device result in an unsafe or ineffective treatment?	X		No accessories required for use.
13) Is safe operation of the device resistant to "typical" handling?			If no, provide plan to mitigate the event

Soft Prolene Mesh DDSA, Rev. 2

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USE RELATED HAZARDS

14.)Could device safety be affected if power is lost or disconnected (inadvertently or purposefully); if its battery is damaged, missing or dead?	х	If yes, provide plan to mitigate the event
15.)Is the status of the device's connection to the patient apparent where necessary?	Х	Device is an implant and does not connect to the patient for feedback/monitoring.

¹Critical steps in setting up and operating the device:

First the mesh is pulled for the case. The circulating nurse makes sure that the proper product was pulled for the case prior to introducing it to the sterile field. The scub nurse will either grab it out of the packet or let if fall on the mayo stand. The mesh is then given to the surgeon by the scrub nurse. If the scrub is familiar with the surgeon's needs he or she may cut or modify the mesh for the surgeon. If not, the surgeon may cut or modify to fit his needs then insert it in the patient. Then the surgeon may attach it in place using sutures, staples or a tacker.

Soft Prolene Mesh DDSA, Rev. 2

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Appendix V

DEVICE DESIGN SAFETY ASSESSMENT (DDSA) FORM Soft PROLENE Mesh Project: Intermediate - Revision 1

INI			THORETON AND THE TRANSPORTED TO THE TRANSPORT OF THE TRAN			te - Nevision 1		
MIMBED	HAZAKD		PROBABILITY	RISK	FAULT	COMMENT	REFERENCES	
_		of HARM	of HAZARD	LEVEL	CLASS			
	Loss of Mechanical				U	Risk acceptable, Material is	DHF: D&D Statement of	
	Integrity					stronger than Mersilene Mesh	Requirements, Material must	
						with same indications. No	exceed strength criteria of	
						action required.	Mersilene Mesh (MS726-001)	
	Unavailable	_	2	_	C	Risk is acceptable,	N/A	
	Operating					unchanged relative to		
	IDSTRUCTIONS					currently marketed device.		
						No Action required.		
	Fraying	_	2	=	<u>ی</u>	Risk acceptable, the	Three bar knitting, by design,	
						resistance to fraying is	limits the ability of the fibers to	
						improved relative to currently	fray along the edges of the	
						marketed Mersilene. No	mesh.	
1						action required.		
	Learing	7	C1	=	ن	Risk acceptable, improved	DHF: D&D statement of	
						relative to currently marketed	requirements and bench-ton	
						Mersilene mesh. No action	feasibility test reports.	
\top						required.	-	
	Suture Pull out	C1	C3	=	×	Risk acceptable, improved	DHF: Feasibility bench-top test	
						relative to currently marketed	report from Ethicon GmbH.	
						Mersilene mesh. No action		
7						required.		
T					1			
_								

Assumptions:

1) Only Personnel skilled in surgery have access to the device.

Soft Prolene Mesh DDSA, Rev. 2

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²⁾ Biocompatibility and toxicology issues are proven as non-existent for PROLENE material.

³⁾ Intended use is defined as implantation for abdominal wall repair.

⁴⁾ Existing Mersilene mesh product is suitable for intended applications based upon historical results.

⁵⁾ Hazards listed are new and unique to the new construction device, packaged as intended to be marketed, relative to Mersilene mesh product

Polypropylene Mesh PROLENE" Soft

Nonabsorbable Synthetic Surgical Mesh



when used as a sulture, has been reported to be non-reactive and to retain its strength excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to Indefinitely in clinical use approximately 50 percent more flexible than standard PROLENE mesh. This material produce contrast striping in the mesh. The imesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh affords polypropylene identical in composition to that used in PROLENE* Polypropylene PROLENE' Soft polypropylene mesh is constructed of knitted filaments of extruded

PROLENE Soft mesh is knitted by a process which interlinks each fiber function and which provides for elasticity in both directions. This construction permits the mesh to be cut listo any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

it subject to degradation or weakening by the action of tissue enzymes. incorporating the mash into adjacent tissue. The mosh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is inflammatory reaction, which is transient and is followed by the deposition of a thin surgical wounds to provide extended support during and following wound healing Animal studies show that implantation of PROLENE mesh elicits a minimum to slight tibrous layer of tissue which can grow through the interstices of the mesh, thus PROLENE Soft mesh is a nonabsorbable mesh used to span and reinforce traumatic or ACTIONS

addition of a reinforcing or bridging material to obtain the desired surgical result. This mesh may be used for the repair of hernia or other fascial defects that require the

CONTRAINDICTIONS

PROLENE Soft mesh in contaminated wounds should be used with the understanding should be aware that this product will not stretch significantly as the patient grows. When this mesh is used in infants or children with future growth potential, the surgeon

that subsequent intection may require removal of the material.

condition or by any other means is neither recommended nor endorsed by ETHICON, INC. PROLENE Soft mesh should \underline{n}_0 be flash autoclaved. autoclave conditions of 250°F (121°C) for 20 minutes. Processing under any other be adversely affected when exposed not more than one time to conventional steam PROLENE Soft mesh that has been removed from the package and reprocessed will not of the device is NOT recommended. However, testing has demonstrated that unused PROLENE Soft mesh is provided by ETHICON, INC. as a sterile product. Resterilization

If this product should become stained with blood or soiled, it should not be resterlized

sterility of the product via a validated sterilization process, as ETHICON, INC. has no control over environmental conditions the product may encounter prior to, during, or When reprocessed as outlined above, it is the responsibility of the and user to assure

A minimum of 6.5mm (1/4') of mesh should extend beyond the suture line.

ADVERSE BLACHOUS

materials, including infection potentiation, inflammation, adhesion formation, fistula Potential adverse reactions are those typically associated with surgically implantable

INSTRUCTIONS FOR USE

than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away. Some surgeons prefer to sulture an uncert section of mesh that is considerably larger (1/4° to 1/2°) apart at a distance approximately 6.5mm (1/3°) from edge of the mesh is recommended that nonabsorbable sutures be placed 6.5mm to 12.5mm

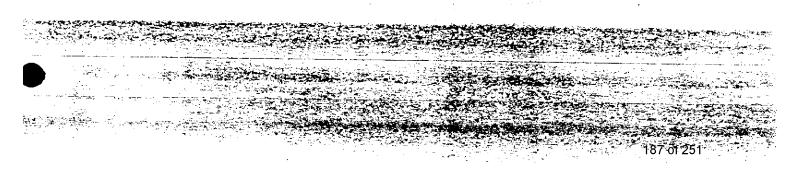
GRITAROS MOR

PROLENE Soft mesh is available in single packets as sterile, clear sheets with

HICON,inc

Somerville, New Jersey 08876-0151 Johnnen Johnson company

SETHICON, INC 2000



OP650-010 CP1998SEF001 Appendix I PRODUCT DI

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PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAG
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PRODUCT DEVICE DESIGN SA	PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAC
DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousscau
ANALYSISTEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services	Charlotte Whiteman
Engineer	
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
DISPOSITION/APPROVAL:	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1
	I deem this analysis to be true and a complete reflection of
	vsis. I find this do
Development Engineer/Scientist	ocsign to be safe for use: (Check one:)
C. C	I deem this analysis to be true and a complete reflection of
	facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use: (Check one:); Yes;: No
A. C. A.	
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis, I find this device
Onality Assurance Engineer	design to be safe for use: (Check one:) X_: Yes;: No
9	
	f deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
	design to be safe for use: (Check one.) : Yes, : No
Regulatory Affairs	

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Medical Director:

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Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE REVISION: DESIGN SAFETY ASSESSMENT

	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE
Product Code:	1_
RMC:	N/A
Project Leader;	Robert A. Rousseau
ANALYSIS TEAM	
Ocvelopment Engineer/Scientist:	
Manufacturing/Technical Services	Charlotte Whiteman
Quality Assurance Engineer.	Michaelle Pamphilo/G O'Brian
Regulatory Affairs: Karen Lessig	Karen Lessig
Product Marketing:	V 7.3. 001 11
DISPOSITION/APPROVAL;	John Janey 3/27/00 AC
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Development Engineer/Scientist	design to be safe for use: (Check one:) . Yes: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use; (Check one.): Yes:: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Quality Assurance Engineer	design to be safe for use: (Check one:) Yes, No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Regulatory Affairs	design to be safe for use; (Check one;); Yes;; No.

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Medical Director;

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Appendix I

PRODUCT DEVICE DESIGN SAFETY ACCESSMENT (DISA)

PRODUCT DEVICE DESIGN SA	PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE
DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services	Charlotte Whiteman
Engineer	
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
DISPOSITION/APPROVAL:	
	I deem this analysis to be true and a complete reflection of
	facts as known at the time of this analysis. I find this device
	design to be safe for use: (Check one:) : Yes; : : No.
Development Engineer/Scientist	
	I deem this analysis to be true and a complete reflection of
Ober Oath. 1. Killer	facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use! (Check one:) 🗸 : Yes;: No.
	I deem this analysis to be true and a complete reflection of facts as brown at the time of this analysis. I find this denies
	S. I THE WILL SE
Quality Assurance Engineer	design to be safe for use: (theck one:): Yes;: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
	design to be safe for use; (Check one:) : Yes; : No.
Regulatory Affairs	!

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Medical Director:

CP1998SEF001 Appendix I

PRODUCT DEVICE DESIGN SA DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
John Ju- 3/2// Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) Yes; : No.
Manufacturing Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
William VIO Kan I'llila	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
Yaren E. Lesteg 3-25 ce Regulatory Affairs	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) : Yes; : No.

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Page 1 of 2

DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT (Revision 1 (Intermediate)- 3/20/00

DEVICE: (Provide a description of the overall device system) A non-absorbable polypropylene mesh, manufactured out of

3.5-mil diameter PROLENE* monofilament fiber. The product is used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing (see attached Product Insert)

SCOPE of the DESIGN SAFETY ASSESSMENT: (Define the scope of this risk assessment)

Device × This risk assessment was completed on (check one):

This DDSA is applicable to the Soft PROLENE mesh product and will identify any hazards associated with this new Component Subsystem

Define the intended use of the reviewed item. product offering.

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (see attached Product Insert)

Briefly describe the revision to the device or sub-system which preceded a revision to the DDSA:

The standard non-absorbable polypropylene mesh currently marketed is manufactured out of 5-mil PROLENE

monofilament fiber with a new knit pattern. This new pattern, coupled with the finer diameter fiber, yields a mesh monofilament fiber. The construction utilized for the Soft PROLENE mesh is manufactured out of 3.5-mil product with larger porosity, lower fabric density and improved flexibility

OP65 U CP195...3EF001 Appendix II

Appendix II Page 2 of 2			
ACTIVITY	YES/NO /NA	FILE REFERENCE	COMMENT
All qualitative and quantitative characteristics that could affect safety have been listed including their defined limits.	YES	D&D Plan & Material Specification #729.	Statement of Requirements & Product Characteristics
The intended use of the device is clearly defined, including:	YES	Product Insert -	Indications Same as for Standard PROLENE Mesh and Mersilene Mesh
Long term use of equivalent product has been considered from both the positive and negative perspective. Clinical/Scientific reports, both internal and published: Device failure reports:	YES	See Performance Requirements/Clinical applications of D&D	Raw Materials and Indications for device are the same as Standard PROLENF mesh.
The contact conditions and timing with the patient have been considered.	YES	See Performance Requirements/Clinical applications of D&D	Ravy Materials and Indications for device are the same as Standard PROLENE mesh.
Materials and components used for fabrication and manufacture have been considered. Chemical nature, quantitative formulation, additives, processing aids, monomers, catalysts, residues: Concentration, availability, toxicity: Biodegradation aging and corrosion: Previous use of this material, and long term effectiveness in equivalent application can be demonstrated: Appropriate Biocompatibility testing to EN 30993:	YES	Soft PROLENE Mesh Biocompatibility Strategy	Raw materials are chemically unchanged – The Standard PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
The sterility of the device and its potential reuse, number of resterilizations possible and sterilization method, device storage, shelf-life, and disposal have been considered.	YES	Product Insert – Warnings section & 1) Sterilization 2) Storage Stability Strategy	Raw materials are unchanged - Standard PROLENE Resin
The accuracy and precision of measurement parameters and their	N/A	N/A	N/A

interpretation has been considered.			
The need for routine maintenance or calibration, and the method of provision has been considered.	N/A	N/A	N/A
Interactions with other devices or drugs, and any potential problems have been considered	YES	N/A	Raw materials are chemically
			unchanged – The Standard PROLENE Resins utilized in
			clear and blue pigmented
Dolor			sutures have been utilized in the fabrication of this mash
Detayed of 10 hg term use, ergonomic and accumulative effects have been considered	YES	N/A	The raw materials utilized in
			the new mesh are chemically
			unchanged. The revised
			construction exceeds the
			burst and suture pullout
			and exhibits a flexibility that
			is greater than Mersilenc
			Mesh and lower than
		-	standard PROLENE mesh.
			Based upon the mechanical
			and chemical criteria utilized
			to develop this material,
			negative tissue responses or
			new negative long term
			implant effects are not
A PBUM has been defined.	No	N/A	Will be defined during
A requirement or finished pands enacification in guesting			development
The state of this shows specification is available.	YES	D&D – Statement of	FG729-002 will be revised
Manufacturing and Material specifications are available	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Requirements	
Surgical technique Jahale warning and other manner of	ONI	V/V	MS 729-006 will be revised
(cleaning, sterilization, use, maintenance, and disposal) are available.	AES A	Product Insert	See package Insert
Device marketing brochures, or other sales literature, have been	Voc	Indiantiana P. C.	

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NIMBED	HAZARD	ll >= -	PROBABILITY RISK FAULT CON	RISK	FAULT	COMMENT	REFERENCES
Magnos -		of HARM	of HAZARD	LEVEL	CLASS		
_	Loss of Mechanical	m	_	=	<u>၁</u>	Risk acceptable, Material is	DHF: D&D Statement of
	٠ • • •					stronger than Mersilene Mesh	Requirements, Material nunst
					_	with same indications. No	exceed strongth criteria of
٠	1 100000011					action required.	Mersilene Mesh (MS726-001)
ì	Onavaliable	_	7	_	O	Risk is acceptable,	N/X
	Operating					unchanged relative to	
	HISTRICTIONS					currently marketed device.	
r+						No Action required.	
٦	rrayıng	_	C)	=	ပ	Risk acceptable, the	Three bar knitting, by design
						resistance to fraying is	Limits the ability of the fibers to
						improved relative to currently	fray along the cdoes of the
						marketed Mersilene. No	mesh,
					_	action required.	
7	l caring	23	7	=	0	Risk acceptable, improved	DHE D&D statement of
						relative to currently marketed	requirements and hence-ton
		•				Mersilene mesh. No action	feasibility test reports.
						required.	
<u>-</u>	Suture Pull out	rsi -	7	=	Σ	Risk acceptable, improved	DHE: Feasibility bench-ton test
					_	relative to currently marketed	report from Pillicon GmbH
						Mersilene mesh. No action	
						required.	

CONTROL PLAN

1) Only Personnel skilled in surgery have access to the device.

ppendix 1X

010-0 *TSion #1 2) Biocompatibility and toxicology issues are proven as non-existent for PROLENE material.

3) Intended use is defined as implantation for abdominal wall repair.

Existing Mersilene mesh product is suitable for intended applications based upon historical results.
 Hazards listed are new and unique to the new construction device, packaged as intended to be marketed, relative to Mersilene mesh product.

998SEE001 Appendix III

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET Soft PROLENE Mesh Project: Intermediate - Revision 1

	COMMENT	If yes, please attach training plan	If yes, please attach plan.	If yes, please define the limits.	If yes, please define the training plan for the user.	If yes, please define the nature of the compromise and the limits.	Permanent prosthetic implant.	Permanent prosthetic implant.	Permanent prosthetic implant.	PROLENE - Polypropylene (blue pigmented and clear). The processes utilized in the manufacture of the material are unchanged relative to standard PROLENE Mesh.	DHF: Biocompatibility Section - 12/2/99 memo from T. Barbolt	No change to raw materials from standard PROLENE.	The Soft PROLENE Mesh is indicated for the same
RESPONSE	YES			ļ !			×	×	×	×	×		×
RES	N/A	×	×	×	×	×						×	
		Is special train needed?	1	Are ther could ir device?		5) Is device safety/functionality compromised based upon the patient (such as elderly, diabetic, handicapped, or other)?	6) Does device use utilize surface contact to the patient?	7) Does device use utilize invasive contact with the patient?	8) Does device use require implantation?	9) Define the materials utilized in the construction of the device. Righlight those materials that will involve direct patient contact	10) Have the materials been tested for toxicity and biocompatibility?	e materials genicity, te icity (as ap	12) Is the strength of load-bearing materials sufficient for the intended use?
	RISTIC	1 Intended Use					2 Patient Contact			3 Materials			

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Mersilene Mesh - MS726-001 and strength than Mersilene. Based the mechanical properties of the Mersilene Mesh, the material has greater suture pull-out mesh, coupled with the same will be sufficient for it's Mesh. The material exceeds produced during the devices strength specification for If no, proceed to the next If no, proceed to the next listing of all by-products applications as Mersilene upon the improvements of intended indications as If yes, please attach a COMMENT in-situ degradation intended use. section. section YES RESPONSE N/A × Soft PROLENE Mesh Project: Intermediate - Revision 1 × 4) Describe the type of energy transferred 13) Is energy delivered to and/or extracted 15) Is the energy output is controlled, in terms of quality, quantity, and time-.6) Are substances delivered to and/or .7) Is the device absorbable? ISSUE extracted from the from the patient? patient? function CHARACTERISTIC 5 Substances Energy

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If yes, please identify the

location of appropriate

the materials identified above been tested

for biocompatibility at the appropriate

concentrations?

substances controlled?

O.f

8) If the device is absorbable, have all of

19) Is the transfer rate (delivery/extraction)

reports,

If yes, please describe how

the transfer rate

controlled

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Soft PRC	Soft PROLENE Mesh Project: Intermediate - Revision 1 3	ion 1			00
		RESPONSE	ONSE		
	ISSUE	N/A	YES	COMMENT	
20)What trans	What is the maximum/minimum substance transfer rate?			If appropriate, please attach required information.	7
21) Are bio device subsequence	Are biological materials processed by the device for subsequent re-use?	×		If not, proceed to the next section.	Doddinie
23)Are mate	those comparials clea			If yes, please specify location of reports.	711C Z OC
24)Are mate	Are those components contacting biological materials compatible?			If yes, please specify location of reports.	, _
25)IS	the device supplied sterile?		×	If not, please proceed to the next section.	
.6) Ide	26)Identify the method of sterilization			Ethylene Oxide - Cycle "J". DHF: Sterility Section- Memo from D.Lasslett	1
27) IS wit	Is the sterilization method compatible with the materials?		×	No change to existing polymer materials and the heat setting process utilized to stabilize the mesh is executed at a temperature approximately three times as great as the temperatures experienced in sterilization.	Tugo oo or
28)Are the steriliz	Are the materials stable after sterilization?		×	No change to existing materials.	
29) Is	the device design sterilizable?		×	No change to existing materials.	90.0
30)Is ste	the package cilization		×	Packaging unchanged from Standard PROLENE Mesh.	
31)Has dete	Has the shelf life of the system been determined?		×	No change to existing materials DAF: Storage	

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1 1 1 1 1	(SE	YES	stability Committee meeting minutes - 12/9/99	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	X No change to existing materials DHF: Storage stability Committee meeting minutes - 12/9/99	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.
/OKKSH on I	RESPONSE	N/A Y		×			×						×		
Soft PROLENE Mesh Project: Intermediate - Revision I 4		ISSUE		32) Is the device re-usable?	33)Are there limitations to the number of reuse cycles?	34) Are there restrictions to sterilization methods utilized by the user of the device?	35)Is the device to be sterilized by the user?	36)Is the method of sterilization and cycle parameters defined?	37)Is the packaging of the product during sterilization specified?	38)Does sterilization validation data exist for the recommended sterilization cycle?	39)Were other methods of sterilization examined?	40) Has the shelf life of the system been determined?	41) Is the device intended to modify the patient environment?	42)What is the effect of temperature on the system performance?	43)What is the effect of humidity on the system performance?
		CHARACTERISTIC					8 Sterility - Supplied Non- Sterile					8 Sterility - Supplied Non- Sterile	9 Environment		

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(-)	COMMENT	If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	If yes, please specify location of reports.	What is the accuracy?	What is the precision?	If yes, please specify location of software walidation reports	If not, please proceed to the next section.	If yes, please specify	If yes, please specify	If not, please proceed to the next section.	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the
RESPONSE	N/A YES			×				×	×			×				
	ISSUE	44)What is the effect of atmospheric gas concentration on system performance?	45)What is the effect of pressure on system performance?	es the	theramet		49) Is the precision of the measurement known?	50) Are conclusions presented by the device based upon measurements, input, or acquired data?	51) Is the device intended to control or interact with other devices or drugs?	52)Does the interaction render any safety or functional changes to the device?	53)Does the interaction render any safety or functional changes to the other device?	54) Are there any unwanted outputs of energy or substances?	55) Does noise affect the device output?	56)Does vibration affect the device output?	57)Does heat affect the device output?	58) Does ionizing radiation affect the device
	CHARACTERISTIC			10 Measurements				11 interpretive	12 Interactions			13 Extraneous Unwanted Energy or Substances				

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14 Environmental

Influences

Environmental

Influences

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بَ	S	If yes, please state the limits.	If yes, please specify	If not, please proceed to the next section,			If not, please proceed to the next section.				If not, please proceed to the next section.			5 Years - No change to	existing materials - DHF; Storage stability Committee		Expiration date labeling (5 vears).	If yes, please specify.	
RESPONSE	N/A YES		×	×			×				×			×		_	×	×	
	ISSOE	73)Does variation in the operating humidity affect the device output of safety?	74)Are there essential consumables or accessories associated with the device?	75)Is preventative maintenance necessary?	76) Can the operator perform preventative maintenance?	77) Is a specialist needed to perform preventative maintenance?	calibrati	79)Can the operator calibrate the device?	Is an e needed?	81) Is the calibration frequency defined?	(X)	83) Can the operator access the software code?	84) Are there means to prevent the operator from modifying the code?	85) Does the device have a restricted shelf			86)Does the package contain an indicator for stability?	87) Are there any delayed or long-term user effects?	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED
*	CHARACTERISTIC		15 Accessories	16 Preventative Maintenance			17 Calibration			0.00	16 SOLUWARE			19 Shelf-life				20 Long-term Effects	